



March 1, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 212441

Dear Administrator Brooks-LaSure:

Submitted via PartDRedesignPI@cms.hhs.gov

RE: CY 2025 Part D redesign program guidance

The MAPRx Coalition (MAPRx) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments regarding the agency's request via the draft contract year (CY) 2025 Part D redesign program guidance issued January 31, 2024.¹

Our group, MAPRx, is a national coalition of beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. The undersigned members of the MAPRx Coalition are pleased to provide CMS with our response to your request for feedback on the Part D benefit redesign for 2025, including on how CMS should 1) evaluate meaningful differences between basic and enhanced standalone prescription drugs plans (PDPs) to help Part D beneficiaries understand the choices offered by a plan sponsor, and 2) protect access and minimize affordability challenges for beneficiaries in the broader Part D redesign.

Changes in True Out-Of-Pocket Costs (TrOOP)

While MAPRx largely supports most of the proposed changes for the various payments included within the TrOOP calculation, we are respectfully seeking clarification on the inclusion of independent charitable copay foundation (ICCF) payments within the TrOOP calculation. While the guidance includes examples such as State Pharmaceutical Assistance Programs (SPAPs) and the low-income subsidy, the guidance fails to mention the assistance provided by ICCFs. As CMS considers this proposal, MAPRx strongly believes the financial support provided by independent charitable copay foundations should be included within the calculation. Similar to assistance provided by SPAPs, this type of charitable support generally has been included in beneficiary TrOOP calculations throughout the benefit. In addition, while the new OOP cap and

¹ CMS. Draft CY 2025 Part D Redesign Program Instructions. January 31, 2024. Accessed February 15, 2024. <https://www.cms.gov/files/document/draft-cy-2025-part-d-redesign-program-instruction.pdf>

the Medicare Prescription Payment Plan (MPPP) will help alleviate financial challenges for standard beneficiaries, many patients may continue to face financial hardships. According to a 2022 poll of Medicare beneficiaries 75% of those polled stated they would still have a difficult time paying \$2,000; this is especially true for beneficiaries that are ineligible for the LIS but below \$50,000 in annual income.² ICCFs have provided millions of dollars in financial support without having a “meaningful influence on Part D gross costs.”³ Given this, there is no foreseeable reason as to why the policy should change under the benefit design. To that end, we believe this financial support is critical for Part D enrollees and should continue to be included within the TrOOP calculation.

CMS notes on page 7 that, unless otherwise stated, guidance for prior years with respect to incurred or TrOOP-eligible costs continues to apply for CY 2025. We take that statement to mean independent charitable copay foundation (ICCF) payments continue to be considered TrOOP-eligible since this type of support generally has been included in beneficiary TrOOP calculations throughout the benefit and CMS does not indicate that is changing for CY 2025. We would appreciate a confirmation from CMS of our interpretation that ICCF payments continue to be considered TrOOP-eligible.

PDP meaningful difference test

MAPRx appreciates CMS’s continued focus on ensuring patients can decipher meaningful differences among plan offerings from a Part D sponsor in a given region. While MAPRx has generally been supportive of CMS’ policy on the meaningful differences, our coalition has significant concerns with CMS excluding utilization management and formulary robustness from determining meaningful differences between a basic and enhanced PDP. Enhanced PDPs are likely to have less utilization management compared to basic PDPs, therefore, this could be a factor in helping to determine meaningful differences. Additionally, with Part D plans likely to expand the use of utilization management as a result of the higher liability under the new redesign, beneficiaries may face greater access challenges.

CMS also stated that it is not likely to move forward with using formulary robustness as a factor in meaningful differences. CMS states that Part D plans may add more drugs to the formulary, but these drugs may have low utilization. While this technically may be true in some cases, many of these drugs may be critical for treating rare and orphan diseases. Additionally, the Part D market has seen a reduction in the overall number of covered Part D drugs in recent years; since 2020, there has been an overall 6% decrease in the average number of branded medications covered by Part D plans, despite a significant number of approvals during each year.⁴

MAPRx recognizes that the absolute percent threshold approach proposed by CMS for CY 2025 could be sufficient in highlighting differences between basic and enhanced PDPs. However, we do not believe this is the most effective approach. With Part D plans likely to narrow formularies and use greater utilization management under the benefit redesign, these measures are the ones that will best help Part D beneficiaries understand the differences between plan options.

² PAN Foundation. Adults on Medicare: financial burden of out-of-pocket costs and impact of a Part D cap. October 2022. Accessed October 2023. <https://www.panfoundation.org/app/uploads/2022/11/Polling-Adults-on-Medicare-Nov2022.pdf>

³ Klein, Dan. Charitable patient assistance is a crucial safety net for millions, but it’s not enough. PAN Foundation. <https://www.panfoundation.org/charitable-patient-assistance-is-a-crucial-safety-net/>. Accessed February 17, 2024. September 2020.

⁴ Cencora analysis of Part D formularies from 2020 to 2024.

Enhanced PDP offerings

As mentioned above, the new benefit design will make it harder for Part D sponsors to differentiate enhanced from basic offerings. Generally, MAPRx supports CMS' conclusion that enhanced PDPs should be evaluated based on their value above the DS Part D drug benefit. MAPRx also supports the process CMS outlined to ensure beneficiaries receive additional value above the DS benefit, since they may be paying higher premiums as a consequence of the Inflation Reduction Act (IRA).

Despite this, utilization of the Part D out-of-pocket costs (OOPC) model to estimate the value of EA plans relative to the value of the DS benefit may not be best metric for defining an enhanced PDP. Given the redesign, CMS will only evaluate reductions in the deductible and cost sharing in the initial coverage phase. And beneficiaries not reaching the OOP cap are the ones to likely benefit in this scenario. To that end, MAPRx respectfully requests that CMS explore other metrics to either replace or augment the OOPC methodology.

Maintaining beneficiary protections through IRA implementation

While not specifically within the context of this subregulatory guidance, CMS' overall approach for IRA implementation will be important for protecting access and minimizing affordability challenges for beneficiaries. To that end, we are sharing some of our primary concerns with implementation moving forward.

Overall, the new benefit design will result in a higher financial liability for Part D plans for patients taking high-cost medications. As an unintended consequence, Part D plans are likely to narrow formulary coverage and restrict access to medications via greater utilization management. Given this, it will be imperative for CMS to maintain strong beneficiary protections. Namely, CMS should maintain its rigorous formulary review process to ensure beneficiaries have access to a wide range of classes and therapies. MAPRx respectfully requests that CMS publicly-release the findings of the formulary reviews so that patients and providers can understand how Part D plans are covering important medications. Additionally, it will be critically important for CMS to maintain the protected classes policy, one that has greatly enhanced access to life-saving medications for countless Part D beneficiaries. Part D plan sponsors are likely to seek ways to manage high-cost medications, including greater flexibility on this policy. CMS must make every effort to maintain this important policy.

In 2023, MAPRx commented on CMS guidance on the Medicare Prescription Payment Plan (MPPP). In February 2024, CMS issued a second guidance with a focus on educational outreach for the new MPPP. MAPRx has been a consistently strong proponent of a true out-of-pocket (OOP) cap in Medicare. Given the critical role this program will play in alleviating financial burdens for beneficiaries, we want to ensure that it is effective in smoothing payments and that CMS is effective in its outreach to beneficiaries who could benefit from the program. Specifically, MAPRx offered the following suggestions for adaptations to the first round of guidance:

- Display a column for patient OOP costs incurred and monthly OOP costs in the monthly billing statement to minimize confusion for program participants.
- Highlight the most important information (eg, total non-itemized OOP costs, OOP costs expected on a monthly basis for the remainder of the plan year) only on the first page of the participant's billing statement.

- Remove the threshold for conducting targeted outreach given congressional intent was focused on making outreach a broad application.
- Reconsider requiring plans and pharmacies to offer real-time or POS enrollment for 2025 as the agency already has reviewed a few feasible ideas.
- Devise and launch a comprehensive educational program to inform prospective participants about this new benefit, specifically for the agency to include information on the program not only in plan marketing materials but also in materials created by the agency (eg, Medicare & You handbook and the Medicare website).

MAPRx has also offered suggestions regarding implementation of the Medicare Drug Price Negotiation Program (MDPNP), specifically that the agency:

- Provides patient organizations ample opportunity and ability to provide feedback on the negotiation process
- Guarantees transparency into how the agency factors external data into its final decisions (including the methodology deployed by the agency)
- Maintains access to a wide range of drugs within Part D and minimizes affordability and access challenges (including on utilization management of negotiated drugs)
- Establishes appropriate guardrails and ongoing oversight processes to continually evaluate the program for the purposes of refining when needed.

Conclusion

Thank you for your consideration of our comments on the draft calendar year (CY) 2025 Part D redesign program guidance. The undersigned members of MAPRx appreciate your leadership to improve beneficiaries' access and affordability in Medicare Part D. For questions related to MAPRx or the above comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

Sincerely,

AiArthritis
 Allergy & Asthma Network
 Alliance for Aging Research
 Alliance for Patient Access
 ALS Association
 American Association on Health and Disability
 American Cancer Society Cancer Action Network
 American Kidney Fund
 Arthritis Foundation
 Foundation for Sarcoidosis Research (FSR)
 GO2 for Lung Cancer
 HealthyWomen
 HIV+Hepatitis Policy Institute
 Lakeshore Foundation
 Lupus and Allied Diseases Association, Inc.
 Lupus Foundation of America
 Muscular Dystrophy Association
 National Kidney Foundation
 National Multiple Sclerosis Society

National Psoriasis Foundation
Patient Access Network (PAN) Foundation
The AIDS Institute
The Assistance Fund
The Leukemia & Lymphoma Society
Triage Cancer